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December 12, 2023

VIA ECF

Honorable Edward S. Kiel, U.S.M.J.
United States District Court, District of New Jersey
United States Post Office & Courthouse
Federal Square, Courtroom 8
Newark, New Jersey 07101

Re: Joint Status Conference Letter
U.S. ex rel Silbersher v. Janssen Biotech Inc.
Civil Action No. 19-12107(MEF-ESK)

Dear Judge Kiel:

Counsel for the parties in the above-referenced matter respectfully submit this joint letter to advise the Court of the status of discovery in this matter in advance of the December 14, 2023 status conference.

I. Party Discovery

A. *Relator's Discovery Requests and Defendants' Responses*

Relator's Statement

1. *Defendants' Due Diligence Prior to Making the Commercial Success Argument*

After many months, Defendants finally provided supplemental interrogatory responses on November 13, 2023. The responses are still deficient, and the parties met and conferred on December 7, 2023.

The most important deficiencies that Relator wishes to resolve, either at the status conference, or by a discovery letter promptly thereafter, relate to interrogatories focused on critical information concerning Defendants' supposed due diligence prior to making the Commercial Success Argument, and the factual bases for Defendants' supposed good faith belief in the

accuracy of the submission.

For example, Interrogatory No. 9 requests Defendants to identify the date and participants of meetings or discussions where the Commercial Success Argument was discussed or analyzed in connection with the prosecution of the patent. Defendants simply refer to their privilege log. But the problem is, Relator has been requesting Defendants to update their privilege log to identify *which* of the supposedly privileged communications relate to the (1) Commercial Success Argument, *versus* (2) patent prosecution of the '438 Patent generally, *versus* (3) other categories of privileged communications. This is the minimum description required under Fed. R. Civ. P. 26, and Relator had understood that Defendants agreed to supplement their privilege log by providing such information during the last status conference. Indeed, by referencing their privilege log in their amended interrogatory responses, Defendants implicitly concede this level of specification is required. Moreover, Defendants are obligated to identify any other meetings where the Commercial Success Argument was discussed (such as telephone or videoconferences even if there are no written communications memorializing them). If Defendants are not going to provide this information, Relator will be forced to file a discovery letter asking the Court to compel.

Moreover, Interrogatory No. 15 requests defendants to "identify all persons and documents" that the patent prosecution attorneys consulted with or relied upon prior to advancing the Commercial Success Argument. In response, Defendants simply referred to various documents that were "produced from Ms. Kamage's files." As Relator has repeatedly explained, Defendants are required to do more. They must identify *which* documents were specifically relied upon as part of the due diligence of the Commercial Success Argument. Additionally, Defendants must confirm that there are no other documents relied upon, regardless of whether they were in Ms. Kamage's custodial files.

Finally, Relator has asked Defendants to "state all facts and reasons" to substantiate Defendants' belief that the claimed invention (coadministration of Zytiga with prednisone) provided Zytiga with a competitive advantage over competing treatments. (Interrogatory No. 4) Relator has also asked Defendants to quantify any such advantage by identifying which portion of Zytiga's commercial success or sales resulted from any such competitive advantage. (Interrogatory No. 5) Defendants have refused to answer these sensible questions, arguing that the specific words "competitive advantage" do not appear in the patent application in that precise order. Relator believes, however, that even if Defendants did not use that specific combination of words, if they believed at the time they submitted the patent application filings, that the claimed invention (*i.e.*, coadministration of Zytiga with prednisone at the indicated doses) provided a competitive advantage over competing products, then Defendants should answer by addressing the substance of the question asked.

2. *ANDA Litigation Documents*

Defendants have produced millions of pages of documents from the ANDA Litigations, but Relator seeks specifically the documents received from specific generic filers that constitute the generic companies' productions that relate to their respective ANDA filings. Because Relator was not part of that litigation and does not know which Bates ranges were specified as responsive to specific requests concerning the generics' ANDA submissions, Defendants should provide that

information to Relator if they have it. The generic companies have consented to this request.

3. *Documents Requested Relating to Kamage Deposition*

On November 21, 2023, Relator served document requests targeted at preparing for the deposition of Andrea Kamage, including all articles published by Ms. Kamage; and internal operating procedures, checklists, or guidance issued to patent prosecution attorneys in Johnson & Johnson's legal department. Defendants say that they will respond by December 21, but they claim that they do not need to produce responsive documents by then. Relator believes these requested documents should not require a large production, and that they are necessary to adequately prepare for Ms. Kamage's deposition. Accordingly, Relator requests that Defendants produce responsive documents by the response date, in accordance with the Request for Production and Fed. R. Civ. P. 34, which by their terms requests to "permit" access to the documents as of the noticed response date.

Defendants' Statement

B. *Defendants' Discovery Requests and Relator's Responses*

1. ***Defendants Have Provided More than Sufficient Interrogatory Responses to Relator.***

As discussed with the Court last month, Defendants provided amended interrogatory responses to Relator in advance of the last conference. To the extent Relator believes he is entitled to more, his requests are premature and unwarranted. Moreover, as this Court has previously indicated, Relator's remaining questions are more appropriate for a deposition and should be raised there.

Although Defendants' interrogatory responses have identified for Relator documents relating to the patent prosecution generally, Defendants have repeatedly advised Relator, the attorney client privilege shields the particular subject matter of Defendants' patent prosecuting attorneys' conversations, which these interrogatories demand. Defendants have been clear with Relator on this position over the past months, and have indicated that Defendants' offer of a limited privilege waiver would resolve Relator's concerns in full. In the event the parties cannot reach an agreement, Defendants have asked that Relator provide legal authority to support his assertion that Defendants' claims of privilege turn on the particular issue of patentability in a particular document (e.g., unexpected results, prior art, or commercial success). Relator has failed to do so. Under Rule 26, Defendants need only provide Relator with sufficient information "to assess the claim " of privilege. Fed. R. Civ. P. 26(b)(5)(A)(ii). Defendants' privilege log more than meets this requirement.

Relator also contends that Defendants have "refused" to provide responses to Interrogatories 4 and 5. That contention is mistaken. Interrogatory 4 requests that Defendants identify "all facts and reasons to substantiate your basis for alleging, during prosecution of the '340 Application, that the claimed invention in the '438 Patent provided Zytiga with a competitive advantage over any competing drug for treating prostate cancer." But, as Defendants indicate in

their response, Relator has not identified any instance during the prosecution where Defendants alleged to the United States Patent and Trademark Office ("USPTO") that the claimed invention "provided Zytiga with a competitive advantage" over competitors. Until Relator identifies the basis for his inquiry, Defendants cannot offer any further response.[1] Relator has offered no justification for his demand to provide the facts and reasons to support an allegation Defendants did not make.

Similarly, Defendants *have* revised their response to Interrogatory 5—which requests that Defendants "identify what portion of Zytiga sales and Zytiga's market share you believe was attributable to, or otherwise resulted from, the claimed invention." As Defendants indicate in their response, they understood the invention claimed by the '438 Patent to be responsible for all of Zytiga's commercial success as well as the factual basis for that belief. As the Court knows, a pharmaceutical manufacturer may market a product only after the FDA has approved its use and labeling. Here, the FDA approved Zytiga for sale and use only in combination with prednisone, which combination is the claimed invention. Hence, the invention contributes to each and every sale of Zytiga. To the extent Relator is dissatisfied with this answer, he is entitled to engage expert witnesses to offer opinion testimony attempting to maintain otherwise. But in any event, this dispute has moved past the discovery stage.

2. *Defendants Have Identified the Generics' Documents from the ANDA Litigation.*

Relator's demand is excessive and unreasonable. Defendants have reproduced the generic manufacturers' ANDA litigation productions in this litigation pursuant to this Court's order and with the consent of the generics. But these documents did not originate with Defendants; rather, Defendants obtained them from the generics in the course of the ANDA litigation. Where the generics have consented, Defendants reproduced the productions to Relator in their entirety, and accompanied by a cover letter indicating specifically which generic's production was included in each particular product. In addition to Bates labels specific to this litigation, the generics' documents are marked with each generic's Bates labels from the ANDA litigation.

Relator now asks that Defendants do far more. Specifically, Relator believes he is entitled to have Defendants sort through the generics' documents and identify specifically those documents he is interested in. Relator offers no justification for this request other that his own belief that Defendants must have the information he's after. But, as discussed above, these are not Defendants' documents. They belong to the third-party generics who actually submitted ANDA filings to the FDA and are therefore best positioned to identify for Relator which documents are their ANDA filings.[2]

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[1] It could be that Relator is conflating "commercial advantage" with "commercial success." The later is a "secondary consideration" that may support a conclusion that an invention was not obvious. "Commercial advantage," on the other hand, is not a recognized "secondary consideration" and appears instead to be something Relator has formulated for this litigation.

[2] Relator indicates that the generics have "consented" to his request. To the best of Defendants' knowledge, *some* of the generics consented to the *reproduction* of their productions from the

3. *Defendants Intend to Comply with the Federal Rules in Responding to Relator's New Document Requests.*

Over the past nine months, Relator has repeatedly delayed in pursuing discovery he believes relevant to his case. For example, in February 2023, before serving a single interrogatory, Relator indicated that he "intend[ed] to schedule an initial round of depositions beginning April 1, 2023." ECF 235 at 2. He still has not taken a single deposition.

Relator has since crafted a new obstacle to taking a deposition. Two nights before Thanksgiving, on November 21, Relator served a new set of document requests on Defendants despite fact discovery being open in this case nearly two years. The requests are not novel, nor do they stem from facts that Relator has learned in discovery. Rather, they seek broad categories of documents—some are publicly available, others are indisputably privileged—that Relator says may inform his deposition of an in-house patent attorney, Andrea Kamage, employed by Defendants. Despite his tardiness in serving these requests, Relator has demanded that they be produced on December 21 prior Ms. Kamage's deposition, and has pressed Defendants for a commitment to produce these documents on an expedited basis.

Defendants have advised Relator that they intend to comply with the federal rules in responding to his request. Under Federal Rule of Civil Procedure 34(b)(2), "[t]he party to whom the request is directed must respond in writing within 30 days after being served." But Defendants must produce those document by time "specified in the request *or another reasonable time specified in the response*." *Id.* 34(b)(2)(B). Defendants are in the process of reviewing Relator's request and conducting the appropriate due diligence necessary to determine what material may be responsive to this request and to assess what responsive material may be privileged. Based on the progress of that diligence process as of December 21 (the deadline for a written response to Relator's new document requests), Defendants will specify a reasonable time for the production of documents responsive to Relator's new requests, as permitted by the Federal Rules.

Defendants' Statement

There are three discovery matters that, in Defendants' view, require this Court's intervention.

1. Defendants Request the Court's Permission to File a Motion for a Protective Order Before Andrea Kamage's Deposition if the Parties Cannot Reach Agreement on the Appropriate Scope of a Privilege Waiver.

The most immediate and important of these issues is defining the appropriate scope of a waiver of the attorney-client privilege to enable Relator to inquire into the patent prosecution while otherwise protecting Defendants' legitimate privilege interests. This can be accomplished through

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ANDA Litigation. Defendants, however, are unaware of any agreement by the generics that Defendants should bear the responsibility for identifying specifically documents within those productions. In any event, as discussed above, the generics are best positioned to identify their own documents for Relator.

either an agreement or a protective order confirming the scope of that waiver.

This issue must be resolved before Relator's proposed deposition of Andrea Kamage—the primary in-house patent counsel for Johnson & Johnson who submitted information to the United States Patent & Trademark Office ("USPTO") that Relator alleges was false and fraudulent. As discussed at the prior status conference, much of the information Relator plans to seek in that deposition is privileged. As a result, unless there is an agreement in place in advance on the scope of Defendants' limited privilege waiver, privilege disputes inevitably will arise in the course of the deposition. This will either require the Court's intervention *during* the deposition or improperly force a second deposition of Ms. Kamage. Both results are unnecessary and inappropriate.

Defendants have been proactive in attempting to resolve this matter, as discussed at length in Defendants' November 29, 2023 Letter (*see* ECF 298), and at the prior status conference. In brief:

Defendants' Limited Waiver Proposal. Relator alleges that Defendants fraudulently procured U.S. Patent No. 8,822,438 (the "'438 Patent") by making false and misleading statements to, or withholding material information from, the patent examiner. Ms. Kamage was the primary in-house patent counsel responsible for that prosecution. In discovery, Relator has served interrogatories and document requests seeking, among other things, information relating to that patent prosecution, including communications and other documents reflecting legal advice Ms. Kamage provided to, and legal services executed on behalf of, Defendants. Defendants have withheld this information as privileged.

To resolve this issue without motions practice, Defendants previously informed Relator and the Court that they are willing to waive the attorney-client privilege to allow Relator to inquire into the patent prosecution, and that such waiver would include the production of privileged, relevant documents. That waiver, however, need extend only to the subject matter of Relator's claims, the prosecution of the '438 patent, and should not extend to Defendants' privileged materials and communications more broadly. To protect those privileges, Defendants prefer to reach agreement on the scope of that waiver prior to the production of privileged documents and prior to Ms. Kamage's deposition, so as to avoid any subsequent suggestion in this litigation or subsequently of a broader subject matter waiver. Additionally, clearly defining the scope of the waiver ahead of time will allow the parties to proceed with discovery more efficiently and significantly reduce the burden on the court refereeing the otherwise inevitable scope disputes.

Status of Negotiations on Defendants' Limited Privilege Waiver Proposal. The parties have met and conferred on Defendants' proposal on multiple occasions, starting on October 12, 2023. At the most recent status conference, the Court advised the parties to continue to do so. On November 29, Defendants submitted a letter to the Court and to Relator that set forth the proposed scope of Defendants' limited waiver. On December 5, the Court ordered that the parties meet and confer on the proposal in Defendants' November 29 letter and to submit their positions in this letter for the Court's review. *See* ECF 300. The parties met and conferred on December 7 to discuss the proposal set forth in Defendants' November 29 letter (ECF 298).

Relator's Notice of Ms. Kamage's Deposition. During the parties' December 7 meet and confer, Relator took the position that he would immediately notice Ms. Kamage's deposition without reaching an agreement on Defendants' proposal and without the further discussion with the Court on this matter that was contemplated in the Court's December 5, 2023 order. The next day, Relator noticed Ms. Kamage's deposition for January 2024.[3] Separately, on the afternoon of December 11, 2023, Relator informed Defendants that he plans to notice a 30(b)(6) deposition, furnished Defendants with a list of 30(b)(6) deposition topics for the first time, and stated he plans to notice the 30(b)(6) deposition for the same day as Ms. Kamage's deposition if Defendants designate her as the 30(b)(6) witnesses. Defendants are reviewing the list of topics to determine the appropriate designee.

Defendants request the opportunity to seek and obtain a protective order prior to Ms. Kamage's deposition, if an agreement between the parties cannot be reached. As stated, it is optimal to define the scope of any waiver of privilege prior to Ms. Kamage's deposition. Defendants submit that the privilege waiver they have offered to Relator is the most reasonable resolution of this issue—especially since Relator has taken no other steps in any attempt to resolve the matter since raising his privilege objections more than six months ago, in May 2023.

As a result, Defendants ask the Court to grant them permission to file a motion for a protective order if the parties cannot reach an agreement on the scope of the limited privilege waiver within a reasonable amount of time (such as 3 business days) after the December 14 status conference. The motion would ask this Court to issue an order confirming the scope of Defendants' limited privilege waiver and confirming that this limited waiver does not effect a broader waiver over other topics. Relator has asked the Court to allow him to brief the question whether Defendants are *required* to waive privilege in response to that motion. Defendants' have no such obligation and Defendants are pleased to address this question further in motions practice on the protective order, if an agreement between the parties cannot be reached.[4]

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[3] Relator noticed Ms. Kamage's deposition for January 8, 2023 in New Jersey. Ms. Kamage (who resides in the San Diego area) is not available for deposition on that date, and Defendants have furnished Relator with alternative dates (January 25-26 and January 31-February 1) and locations (Los Angeles) where she would be available, provided that a protective order is implemented in advance—either by agreement of the parties or by this Court's order.

[4] In making the argument that Defendants are *required* to waive privilege, Relator quotes from—and misunderstands—an article published by Ms. Kamage nearly twenty years ago. That article describes the then-existing state of the law in the Federal Circuit with respect to inequitable conduct, which allowed aggressive use of that doctrine in ordinary patent litigation. But, what Relator omits is that the Federal Circuit—relying on many of the same concerns Ms. Kamage had raised in her article—subsequently changed the legal standard for inequitable conduct and, thus, Ms. Kamage's observation in that article no longer describers the operative legal standard. As Ms. Kamage states in her article, courts at the time had "lowered the bar" for finding inequitable conduct and were "inferr[ing]" that the Defendant had the intent to deceive the PTO if the defendant could not put forth "a credible, good faith explanation from the patent holder." *See id.* In other words, the old Federal Circuit test put the burden of proof on the *defendant* to establish

Defendants do not want the parties' inability to reach an agreement on this issue to unnecessarily delay discovery generally or the deposition of Ms. Kamage in particular. Defendants first raised this proposal with Relator more than two months ago, on September 28, 2023, and Defendants submit that the parties have had ample time to negotiate. Defendants submit that it is therefore appropriate to allow them to file a motion for a protective order if an agreement cannot be reached promptly.

Defendants ask the Court to stay Ms. Kamage's deposition until the Court has the opportunity to consider and rule upon Defendants' motion for a protective order. In addition, if the parties cannot reach an agreement, Defendants respectfully ask this Court to rule upon their motion for a protective order before Ms. Kamage's deposition occurs. To enable the Court to appropriately consider the motion and allow Relator an appropriate opportunity to respond, Defendants ask this Court to stay Ms. Kamage's deposition until this Court issues its ruling on the protective order motion.

Defendants are prepared to move forward with Ms. Kamage's deposition promptly after this Court's decision is reached. Further, as Defendants have already stated to Relator, to minimize

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that it lacked intent to deceive the PTO. *That* is the reason why Ms. Kamage observed in her article that, under the old standard, a defendant cannot "rely on an accuser's inability to provide evidence of intent," must affirmatively submit evidence of its lawful intent, and that "[w]aiver of attorney-client privilege *may* be necessary" to do so. Andrea Kamage & Deborah Sterling, "The Patent Plague; Smart Pills," 5 Intellectual Property Law & Business, at 18 (Aug. 2005) (emphasis added).

The Federal Circuit subsequently rectified the legal standard, however, and properly placed the burden of proof back on the plaintiff where it belongs. In *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), the Court held that "[b]ecause the party alleging inequitable conduct bears the burden of proof, "the patentee *need not offer any good faith explanation* until the [party asserting inequitable conduct] proves a threshold level of intent to deceive *by clear and convincing evidence*." *Id.* at 1291 (cleaned up) (emphases added). And in rejecting earlier decisions that held otherwise, the Court made clear that "[t]he absence of a good faith explanation . . . does not, by itself, prove intent to deceive." *Id.* In sum, Ms. Kamage's article does not describe the existing state of the law. In addition, it is beside the point. Defendants have offered a limited waiver over the attorney client privilege; the only issue to be resolved in the scope of that limited waiver. Relator similarly misrelies on Judge McNulty's decision on Defendants' Motion to Dismiss, which does not address either of the issues raised in Relator's footnote: namely, which party bears the burden of proof (Relator) or the proper scope for a privilege waiver.

Lastly, Relator's commentaries on *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751 (2023), are an attempt to pre-litigate issues that will be raised at summary judgment. If Relator wishes to resolve legal issues that bear on his claims, he should do so in such a motion rather that a status letter to this Court. *Schutte* addressed the scienter standards required under the False Claims Act; it did not address whether, a Relator alleging underlying violations based on inequitable conduct must actually prove inequitable conduct.

any delays associated with the stay, they are also willing to agree to provisional dates for Ms. Kamage's deposition, on the condition that the deposition will move forward only if the privilege waiver issue has been resolved through a mutual agreement (approved by this Court) or this Court's ruling on a protective order motion, if necessary.

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Defendants have been diligent in attempting to resolve this issue without the Court's intervention for weeks, and request the opportunity to seek and obtain the Court's intervention before Ms. Kamage's deposition if an agreement between the parties cannot be reached.

2. Relator Has Failed to Produce Any of Relator's Redacted Patent Consulting Advice.

As discussed in the parties' prior joint letter and the November status conference, Relator has yet to produce any non-privileged memoranda provided to clients in his consulting capacity that relate to the patent topics at issue in this case.[5] When this matter was discussed at the last status conference, the Court instructed Relator to commit to a date certain upon which he would complete these productions. Relator stated that the productions would be completed before the end of December and represented that he would endeavor to make rolling productions starting *before* the December 14 status conference. Relator has not yet made any such productions in response to this request.

At the status conference, Defendants respectfully request that the Court direct Relator to complete these productions before December 31, 2023, as previously discussed. Alternatively, Defendants request the Court's leave to file a motion to compel the production of the disputed materials.

3. Relator Has Not Provided All Requested Revisions to His Deficient Interrogatory Responses.

The parties previously submitted a joint discovery dispute letter regarding Relator's deficient responses to multiple of Defendants' interrogatories. These interrogatories seek information that is foundational to Relator's case, including asking him to identify with specificity any and all misleading statements or material omissions he now alleges as part of his claim. At the prior status conference, the Court and the parties agreed that Relator would provide Defendants with amended responses to these responses no later than December 1, 2023. On December 1, 2023, Relator provided Defendants with revisions to only *some*—not all—of the deficient interrogatory responses he indicated he would amend. Defendants intend to continue to meet and confer with Relator regarding his amended responses. They have requested that Defendant provide

[5] In an October 12 meet-and-confer, the parties agreed that Relator could redact the identities of clients found in those documents, but failed to reach agreement on other redactions that Relator sought to make. To facilitate a resolution, Defendants indicated that Relator should proceed with his production of the documents with redactions as Relator saw fit, with the understanding that Defendants reserved the right to challenge any redactions beyond the clients' identities.

a further date when they can expect the agreed upon revisions. Relator has yet to provide one.

Relator insists that Defendants only requested—and the Court only directed Relator to provide—revised responses to the subset of interrogatories that are substantively briefed in the prior dispute letter. But as Defendants explicitly stated in the prior dispute letter—and as Relator did not dispute in that letter or at the prior status conference—Relator had represented during meet and confers that he would be revising his responses to six other interrogatories. *See* ECF 294 at 6 ("To the best of Defendants' understanding, Relator's counsel has committed to Defendants counsel that Relator will provide revised responses to the following Interrogatories: 1, 4 (in part, 9, 10, 11, and 19. "). Because of Relator's representation, Defendants did not substantively brief those six interrogatories in the dispute letter because Relator had committed to revising them without the Court's intervention. Relator made no attempt to disclaim his commitment to revising the interrogatories in the prior dispute letter, as he even argued to the Court in that letter that he *had* committed to revising his interrogatories. *See id.* at 4–5 ("Relator has been clear with Defendants that . . . he would supplement his interrogatory answers to add the additional facts.").

Relator now takes the position that he need not revise the additional responses that were not substantively briefed in the dispute letter. This would set a dubious precedent that is likely to waste the Court's time and resources. As the Court's rules contemplate, the parties are required to meet and confer in good faith to resolve discovery disputes without seeking the Court's intervention. If Defendants cannot rely on Relator's commitments—most importantly, those that Relator has made representations about to this Court—Defendants will be forced to raise every minute discovery issue with the Court. That is not how litigation should operate.

At the status conference, Defendants respectfully request that the Court direct Relator to commit to a date certain on which he will produce revised interrogatory responses.

Relator's Statement

1. If the Parties Cannot Reach an Agreement on a Partial Waiver by the Status Conference, then the Court Should Determine the Effect of any Assertion of Privilege *Vel Non* on a Full Record after Ms. Kamage's Deposition.

Defendants unilaterally filed their November 29, 2023 letter, without any prior notice to Relator, and they spill much ink discussing whether a patent prosecution attorney's communications are privileged. They miss the important question, which is whether Defendants can have their cake and eat it too: Can they shield patent prosecution counsel's diligence under a claim of privilege, while at the same time preserving their right to argue that their diligence concerning the submission of the Commercial Success Argument was reasonable?

Recognizing that they are required to waive privilege concerning patent counsel's diligence in submitting the Commercial Success Argument if Defendants intend to defend the reasonableness of such diligence,[6] Defendants say that they have offered to "partially waive"

[6] Indeed, there can be no question Defendants had not expectation that the communications of their patent prosecution counsel would be protected by privilege if they were sued for fraud

privilege by (according to them) providing information concerning "the subject matter of Relator's claims" and "the prosecution of the '438 patent." What Defendants omit is that Relator has offered to accept the literal scope of such a partial waiver on its face, stating that any such partial waiver naturally extends to the specific issues Relator identifies in Paragraphs 84 and 87 of the complaint, in addition to any information relating to whether Defendants viewed prednisone coadministration as being a significant barrier to the acceptance of Zytiga against competing treatments that did not require coadministration. These clearly identified bases for fraud certainly are part of the "subject matter of Relator's claims." Defendants, however, have rejected Relator's clarification, which confirms that Defendants' view of the "subject matter of Relator's claims" is unreasonably blinkered and not as broad as what their proposal seems to imply.

As a concrete example, Relator posed the following scenario to Defendants: What if, prior to submission of the Commercial Success Argument, Ms. Kamage received an email stating that if Defendants did not evergreen their patent monopoly by December 2016, then Defendants would lose their exclusive license monopoly afforded by the '213 blocking patent,

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relating to the patent application. The lead patent prosecution attorney for Defendants, Andrea Kamage, publicly acknowledged that "if a patentee wants to avoid a finding of inequitable conduct, then the patentee can't rely on an accuser's inability to provide evidence of intent. Instead, the patent holder better have a good explanation for his conduct. Providing an explanation can come with a cost. Waiver of attorney-client privilege may be necessary in order to produce documentation of a good-faith explanation." Andrea Kamage & Deborah Sterling, "The Patent Plague; Smart Pills," 5 Intellectual Property Law & Business, at 18 (Aug. 2005).

Defendants argue that Ms. Kamage's statement no longer applies because the Federal Circuit raised the standard for inequitable conduct scienter. However, since the time Ms. Kamage wrote that article, things have actually gotten much worse for Defendants, because the Supreme Court of the United States has recently confirmed by a unanimous decision in June 2023 that the scienter standard under the False Claims Act is far less stringent than what would apply to an inequitable conduct defense in a patent infringement action. That decision—which was briefed and argued by undersigned counsel Tejinder Singh—held that False Claims Act scienter can be satisfied if defendants are "aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statements' truth or falsity"; and even if defendants are "conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751 (2023). Thus, even though the standards for inequitable conduct were later raised by the Federal Circuit, the opposite happened in the False Claims Act context. Therefore, Ms. Kamage's statement continues to this case *a fortiori*—a fact consistent with Judge McNulty's decision in this case rejecting Defendants' motion to dismiss. *See United States ex rel. Silbersher v. Janssen,* 576 F. Supp.3d 212, 230 (D.N.J. 2021) (rejecting application of heightened inequitable conduct scienter to FCA claims, holding that there is no "justification for Defendants' attempt to shoehorn antitrust caselaw from the Federal Circuit into this case").

which was responsible for at least 90% of Zytiga's market share? Certainly, that would be a relevant document, and it's clearly identified in Paragraph 87(e) of the operative complaint. Why should such a document be excluded (or any other communication relating to the bases of fraud listed in the complaint)? Defendants gave no response, other than to say that they will try to come back with an acceptable proposal later.

If the parties cannot agree on the scope of a partial waiver, Relator believes that the most efficient way to resolve this dispute is as follows:

- The deposition of Andrea Kamage should commence as noticed in early January 2024.[7] Thereafter, the parties can brief the consequences of Ms. Kamage's answers to specific questions based on a full record. Indeed, it would be difficult to determine the scope of any "partial" waiver without knowing the precise questions that Ms. Kamage either answers or refuses to answer based on privilege.

- *Alternatively*, if the Court is inclined to determine the issues raised by Defendants prior to Ms. Kamage's deposition, then the parties should be ordered to submit a joint letter concerning whether Defendants must waive privilege if they intend to submit evidence concerning the sufficiency of patent prosecution counsel's due diligence prior to submitting the Commercial Success Argument. Defendants say that they intend to focus only on the scope of any waiver should they choose to answer a particular question, but that question is intertwined with the more fundamental issue of whether Defendants are permitted to present evidence suggesting that they conducted an adequate and reasonable due diligence sufficient to satisfy *Schutte* (*see* fn. 6, *supra*) without waiving privilege relating to such diligence or lack thereof. Thus, any "partial" waiver must embrace the entire subject matter as to which the question relates, *i.e.*, Defendants' due diligence or lack thereof under the *Schutte* standard.

  - ✓ Relator further proposes that the parties submit any such joint letter within one week of the December 14, 2023 status conference, unless the parties reach an agreement on a partial waiver before then.

2. Relator Will Produce Response Documents by December 31, 2023.

Relator does not understand why Defendants have included this issue in their letter, weeks before the due date for the documents.

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[7] Defendants imply that they provided alternate dates, and Relator has been uncooperative. This is not true. On the same day that Defendants offered dates in *late* January 2023 in San Diego, Relator's counsel responded that Relator (a) would be willing to consider a deposition in Southern California, and (b) counsel would be flexible with dates based on actual unavailability. Relator simply insisted that he did not want to wait until the end of January without a representation that Ms. Kamage or counsel were *unavailable* before then (as opposed to merely preferring to delay the deposition). Defendants have not responded to Relator's message.

3. Relator Supplemented the Interrogatories that Defendants Requested.

Defendants' statement is not accurate. Defendants' November 14, 2023 discovery letter (ECF No. 294) specifically requested supplemental responses to Defendants' interrogatory numbers **4 through 7**. Relator provided timely supplemental responses to these and other interrogatories on December 1, 2023. Indeed, Relator notes that Defendants never try to specify what information they actually wanted that was not provided. Nevertheless, Relator has further agreed to address Defendants' further objections, even though he disagrees they are required. For example, Defendants insist that Relator should identify in Interrogatory No. 19 the bases for fraud that were *not* raised in the ANDA Litigation. That's dififcult to understand, particularly in light of the fact that Defendants haven't even provided complete documents in the ANDA Litigation. Defendants are now merely insisting that Relator copy and paste the bases for fraud he has *already* identified in his supplemental interrogatories relating to this precise issue, instead of simply referring to those answers. This is simply not worth wasting the Court's time.

To be clear, Relator's answers to the interrogatories were not deficient. In fact, Defendants complained at the last status conference that the references to the very detailed allegations in Paragraphs 84 and 87 of the complaint were *too detailed* and loaded with so many specific allegations of fraud that the descriptions ran over eight (8) pages. Defendants' gripes with Relator's answers is that Relator did not copy and paste the specific allegations included in the complaint directly in Relator's answer, and *not* that Relator kept information from Defendants. Relator has now done so.

II. Government Discovery

Relator's Position

Relator have agreed, along with the Centers for Medicare and Medicaid Services ("CMS"), for the Court to enter an order directing the Clerk of the Court to sign a subpoena to CMS seeking data relating to Medicare payments for Zytiga and generic alternatives. The Court signed a similar stipulation and order with respect to the United States Department of Veterans' Affairs (the "VA") on November 27, 2023 (ECF No. 297), although Relator is still waiting for that signed subpoena to serve on the VA.

CMS requests that prior to providing Medicare data requested, which may include patient health and patient identifying information, that the Court enter a HIPAA-compliant protective order that meets the requirements of CMS. Accordingly, CMS has provided a proposed confidentiality order that it believes should be entered prior to production of the data requested in the subpoena (attached as **Exhibit A**).

Relator agrees to the proposed confidentiality order requested by CMS and believes that the Court should approve and enter the order forthwith so that discovery can continue expeditiously. Defendants, however, have objected to a separate confidentiality order governing CMS's information, without providing much in the way of a specific objection. Relator requested Defendants to specify the basis for their objection during the parties' meet and confer on December 7, 2023. The only issue that Defendants raised was the possibility that legal support staff may be

required to sign an acknowledgment form (and therefore too burdensome), even though CMS's proposed agreement states that "entry of this Protective Order by the court will constitute Acknowledgement by the Parties and their legal counsel" and that "an officer or manager of the entity may sign" on behalf of the entire entity, reducing any potential burden on Defendants. (*See* Ex. A, at ¶ 8) Accordingly, Relator believes that Defendants have raised no issue that should prevent the Court from entering the proposed confidentiality order that would apply only to information produced by CMS.

Defendants' Position

As the Court may recall, the parties to this litigation—as well as several parties long since dismissed—spent substantial time negotiating an agreed-upon confidentiality order to govern discovery in this action. *See* ECF 175. That order applies both to the production of both parties' and non-parties' documents alike. Despite the existence of that order, Relator now seeks to enter an additional order, which will purport to bind all parties in this action. Relator's attempt to do so is both procedurally improper and premature.

On November 21, 2023, Relator first indicated to Defendants that CMS requested that the parties agree to the entry of an additional confidentiality order to govern the production of CMS material in this action. Because Defendants were not party to Realtor's discussion with CMS, Defendants indicated to Relator that they would not blindly consent to the entry of an additional order. Defendants, however, asked for additional information regarding the need for such an order—particularly in light of the pre-existing confidentiality order. Relator refused to provide one beyond his reiterating that CMS has requested the entry of such an order. During the parties' December 7, 2023 meet and confer, Defendants suggested that all three parties—Defendants, Relator, and CMS—meet and confer to discuss the entry of such an order, including any provisions of the preexisting order that CMS believes were insufficient and necessitated the entry of an additional order. Relator, however, refused to facilitate that discussion.

To be clear, Defendants do not object outright to the modification of the standing confidentiality order to accommodate CMS's concerns, or the entry of an additional order should good cause require it. But Defendants have the right to be informed of the need for such an order, and Relator and/or CMS are required to make that showing. Indeed, "it is well-established that a party wishing to obtain an order of protection over discovery material must demonstrate that 'good cause' exists for the order of protection." *Castellani v. City of Atlantic City*, 102 F. Supp. 3d 657, 666 (D.N.J. 2015) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994)). Relator made no attempt to do so, and instead insists that it is Defendants who bear the burden of showing that such an order *not* be entered. That is not Defendants' burden. Moreover, the this Court's local rules require that "[a]ny dispute regarding the entry of an order, or the confidentiality of discovery materials under any order, under this section shall be brought before a Magistrate Judge pursuant to L. Civ. R. 37.1 (a)(1)." Relator has not done so.

As Defendants advised Relator, a simpler path forward exists. *All* of the interested parties should meet and confer on the issue: CMS, Relator, and Defendants. Defendants request that the Court order that the parties do so.

III. Other Issues

The parties agree that no issues other than those described above need be addressed at this time.

Respectfully yours,

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